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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,587	05/03/2002	Dan L. Eaton	P3230R1C001-168	4546

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EXAMINER

KAUFMAN, CLAIRE M

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/063,587

Applicant(s)

EATON ET AL.

Examiner

Claire M. Kaufman

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/13/02</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC §§ 101/112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to an antibody which specifically binds the polypeptide of SEQ ID NO:78. The specification asserts a number of utilities for both the polypeptide and encoding polynucleotide, however, these utilities are not specific and substantial or well established. If the polypeptide antigen does not have utility, then the antibody which binds it does not have a specific and substantial utility. For example, in Example 11 (page 133), it is asserted that the polypeptide may be used as an antigen to make antibodies. Because neither the physiological nor the clinical significance of the polypeptide is known, and because the prior art does not support a very close structural relationship to a well described family of known proteins by both structure and function, the polypeptide does not have utility as required by 35 USC 101. If one does not know what the protein to which the antibody binds does or what disease it is specifically associated with, then the antibody that binds the protein likewise does not have utility. The ability to isolate a protein, detect expression changes of the protein and diagnose disease by using an antibody is not a specific or substantial use if it is not known what the isolated or expressed protein does or what specific disease can be diagnosed with it.

Another possible utility comes for the finding that the encoding polynucleotide is "more highly expressed" in normal stomach and lung as compared to stomach and lung tumor tissue (Example 18, p. 142). There is no guidance on how to use this information. No levels (relative or absolute) are disclosed. This information is too sparse to allow the encoding polynucleotide to

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be used as a diagnostic marker for stomach or lung tumor. Further, even if the polynucleotide had utility as a tumor marker, the antibody binding the encoded polypeptide has no such utility since there is no reason to suspect that there is alteration of polypeptide sequence or amount in stomach or lung tumor *versus* normal tissue. It is not known what the protein does or if the level of the protein of SEQ ID NO:78 in stomach or lung tumors corresponds to nucleic acid transcript level, *i.e.*, if decreased gene amplification in tumors corresponds to a decrease in amount of expressed protein.

Lastly, in Figure 78, it is indicated that the polypeptide shows some structural similarity to LBP, BPI and CETP family proteins; however, the type of relationship is not disclosed. No important features common to all the proteins are disclosed. The level or pattern of the similarity is not discussed. The skilled artisan could not use this information to establish a specific and substantial use the claimed polypeptide or antibody which binds it.

For these reasons, there is no substantial and specific utility for the claimed antibody.

Claims 1-6 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

It would require significant further experimentation to be able to use the claimed antibody because no definite function or directly associated disease has been determined for the protein of SEQ ID NO:78. No function can be reasonably assigned to the polypeptide antigen based on its homology to another protein(s).

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 6 and dependent claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 recites an antibody that “binds”, while the antibody of claim 6 “specifically binds”. The specification (§[0247] of p.42) defines “specifically binds to” as binding to the target polypeptide “without substantial binding to any other polypeptide or polypeptide epitope.” The term “substantial” makes the metes and bounds of the claims confusing. It is not clear how binding of the antibody of claim 1 and claim 6 differ.

35 U.S.C. § 102

The following rejections under 35 U.S.C. § 102 are made under the assumption that the effective filing date for the instantly claimed invention is 05/03/2002, which is the actual filing date of the instant application. Applicant is advised that the instant application can only receive benefit under 35 U.S.C. § 120 from an earlier application which meets the requirements of 35 U.S.C. § 112, first paragraph, with respect to the new claimed invention. Because the instant application does *not* meet the requirements of 35 U.S.C. § 112, first paragraph, for the reasons given above and it is a continuing application of Serial Number 10/006,867, the prior application also does not meet those requirements for the claimed invention and, therefore, is unavailable under 35 U.S.C. § 120.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/161318.

WO 01/161318 teaches the polypeptide of SEQ ID NO:78 (see Fig. 78) and a monoclonal antibody that binds it (Example 10 beginning p. 88, and claim 17 on page 102). Also taught are humanized and labeled antibodies as well as an antibody fragment (p. 69-70, lines 23-30, p. 75, lines 17-24, and p. 69, lines 19-21, respectively).

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Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/12708.

WO 00/12708 teaches the polypeptide of SEQ ID NO:78 (see Fig. 78) and an antibody that binds it (*e.g.*, p. 296, lines 27-29).

Conclusion

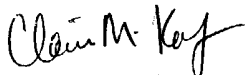
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday and Thursday from 8:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (703) 872-9306. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

June 17, 2004